UNITED STATES District Court
Northern District of Illinois
EASTERN Division

Rodney Patton
v.
Wilvis Harris

FILED
APR 21 2008
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MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

08 CV 1975

Motion for Reconsideration

Now comes the Plaintiff Rodney Patton pro'se, And ask this Honorable Court to reconsider the Plaintiffs complaint, the following is stated:

1. The Plaintiff states that Defendant Harris with Held EXCulpatory Evidence concerning the way the test was administered, which cause a false positive result, as explained in the ~~Attached~~ exhibit.

2. I have learned that the urine test is inaccurate when the test cup is reused, And the Defendants KNEW this and withheld this information from the Plaintiff.

3. The Plaintiff Complaint should not be dismissed for failure to state A Claim unless it appears beyond doubt that the Plaintiff can prove no set of facts in support of my Claim which would entitle the Plaintiff to relief. Cruz V. Beto, 405 U.S. 319, 322 (1972)

4. The Plaintiff states that the defendant's have been using this test Device before the Plaintiff was ask to provide a urine sample on 10-4-07, And had full Knowledge that the manufacture has stated that the test cup is not to be reused.

5. The Plaintiff states that at the time of filing my complaint I lack the knowledge of this type of information, and the new information goes to support the Plaintiff complaint fully. (Note Attach)

6. The Plaintiff ask the court to reconsider it's ruling, and Allow the Plaintiff's complaint to continue base on this new evidence which will allow the Plaintiff to seek relief as a result of a civil rights violation.

7. The Plaintiff ask the court to Allow me to Amend my complaint because I will be Adding different fact base on the new evidence, And a legal claim.

8. The Plaintiff states that this new evidence was mailed to the Plaintiff after my complaint was filed with the court.

9. The Plaintiff ask the court to allow me a chance to amend my complaint base on this new evidence, especially when this ~~information~~ shows a civil right violation. Riccuti v. N.Y.C. Transit Authority 941 F. 2d 119, 123 (2d cir. 1991)

10. The Plaintiff complaint along with this new evidence meets the courts standards and does state a claim on which relief can be granted, The court is ask to grant leave to amend my complaint. Foman v. Davis, 371 U.S. 178, 182 (1962)

Wherefore the Plaintiff ask the Court to Reconsider it's ruling and allow the Plaintiff leave to amend.

Respectfully Submitted,

Dated April 17, 2008 * filed timely

Phamatech, Inc., 9530 Padgett Street, Suite 101 San Diego, CA 92126 USA
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QuickScreen™ Cup Multi Drug Screening Test

Catalog # 9177X-25

Test Instructions

Intended Use

The QuickScreen™ Cup Multi Drug Screening Test is a rapid, self-timed, qualitative immunoassay for the detection of drugs of abuse in urine. The cutoff concentrations for this test are PCP at 25 ng/mL, Amphetamine at 1000 ng/mL, THC metabolite (THCA) at 50 ng/mL, Cocaine metabolite (Benzoylecgonine) at 300 ng/mL and Opiates at 2,000 ng/mL. This assay is intended for professional use.

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

Summary & Explanation of the Test

Phencyclidine, also known as "Angel Dust" or PCP, is used primarily as a recreational drug for its hallucinogenic effects. Commonly eaten, inhaled, smoked or injected, it is well absorbed by all routes of administration, concentrating fastest in fatty tissues and in the brain. Unchanged PCP is excreted in the urine in moderate amounts (10% of the dose). The terminal half-life for PCP varies considerably, ranging from 8 to 55 hours, averaging 18 hours. The effects of this drug are unpredictable and variable. Users may exhibit signs of euphoria, anxiety, relaxation, increased strength, time and space distortions, panic and hallucination.

Amphetamine (AMP) and its metabolites are central nervous system stimulants whose pharmacological properties include alertness, wakefulness, increased energy, reduced hunger and an overall feeling of well being. Large doses and extended usage can result in higher tolerance levels and physiological dependency. Both d and l forms of Amphetamine are controlled substances.

Δ^9-Tetrahydrocannabinol (THC) is generally accepted to be the principle active component in marijuana and hashish, although other cannabinoids contribute to their physiological activity. THC is rapidly absorbed by inhalation and by the gastrointestinal tract, and is almost completely metabolized. Its predominant metabolite, 11-Nor-Δ^9-THC-9-carboxylic Acid, or THCA, is found in the plasma, feces and urine along with other compounds. Low concentrations of THC may be detected in urine during the initial several hours, but THCA persists in urine at a detectable concentration for many days after smoking.

Cocaine (COC) is an alkaloid present in coca leaves (*Erythroxine coca*) whose pharmacological properties include alertness, wakefulness, increased energy, and an overall feeling of euphoria. Cocaine has been used medicinally as a local anesthetic, however, its addictive properties have minimized its modern value as an anesthetic. Elimination of cocaine is predominantly controlled by its biotransformation. It is almost completely metabolized to Benzoylecgonine. Very low concentrations of Cocaine may be detected in urine during the initial several hours, but Benzoylecgonine persists in urine at detectable concentrations for 48 hrs.

Opiates (OPI 2000) are addictive, pain-relieving narcotic drugs derived from the opium poppy (*Papaver somniferum*). An opiate is any natural or synthetic drug derived from this plant that has morphine-like pharmacological actions. Natural opiates include Codeine, Morphine and Thebaine. Synthetic opiates include Heroin, Hydrocodone and Levorphanol.

Urine based screening tests for drugs of abuse range from complex analytical procedures to simple immunoassay tests. The sensitivity and rapidity of immunoassays have made them the most accepted method of preliminary screening for drugs of abuse in urine. This allows the laboratory to eliminate the large number of negative specimens and focus on the smaller number of initially positive samples.

Principle of the Procedure

The QuickScreen™ Cup Multi-Drug Screening Test is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is a chromatographic absorbent device in which drugs or drug metabolites in a sample compete with drug / protein conjugate immobilized on a porous membrane for a limited number of antibody / dye conjugate binding sites. The test device employs a unique combination of monoclonal and polyclonal antibodies to selectively identify drugs of abuse in urine with a high degree of confidence. The test device also contains a self-timer that indicates when test results are ready to be interpreted.

In the procedure, a fresh urine sample is collected directly into the cup. The urine is absorbed into each test panel by capillary action, mixes with the antibody / dye conjugate, and flows across the pre-coated membrane. **When sample drug levels are below the target cutoff** (the detection sensitivity of the test), antibody / dye conjugate binds to the drug / protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test Band that, ***regardless of its intensity***, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody / dye conjugate, preventing the antibody / dye conjugate from binding to the drug / protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band, indicating a potentially positive sample.

In either case, a colored Control Band is produced in the Control Region (C) by a non-specific antibody-dye / conjugate reaction. This band serves as a built-in quality control device, demonstrating antibody recognition and reactivity as well as confirming that the test is complete.

Reagents & Materials Supplied

1. 25 "Self-Timed" Test Cups (Cat. # 9177X). Separate test panels for each target drug contain:
   a. Monoclonal anti-drug antibody / colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
   b. Drug derivative / protein conjugate immobilized as a line in the Test Region (T)
   c. Goat anti-mouse antibody immobilized as a line in the Control Region (C)
2. Directional Insert (Cat. # 9177X-DI)

Plaintiff was Entitled to Second Cup Test Device →

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Warnings & Precautions

1. FOR PROFESSIONAL, *IN VITRO* DIAGNOSTIC USE ONLY
2. This method is established using urine only. No other fluid has been evaluated. Urine has the potential to be infectious. Follow Universal Precautions for proper handling and disposal methods.
3. Do not use this kit beyond its expiration date. Do not reuse the Test Device.

Storage & Handling Requirements

Store at room temperature (15 – 28 °C). Do not freeze. Refer to expiration date for stability.

Sample Collection & Preparation

A fresh urine sample should be collected in the cup device immediately prior to testing. The urine should be collected to the recommended volume indicated by the "FILL TO HERE" mark on the outside of the cup. Examine the temperature strip within 1 minute after collecting the specimen. The temperature should be between 90 and 100 °F. Samples outside this range may have been adulterated.

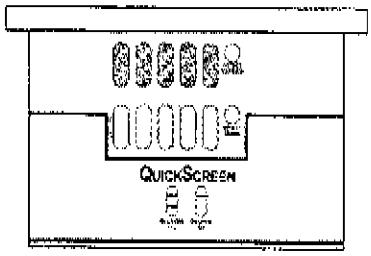
Assay Procedure

Preparation

1. Confirm that the cup device is at room temperature (15 – 28 °C) before testing.
2. Do not break the seal on the on the lid until you are ready to perform the test.

Testing

1. Open the foil pouch, remove the test device, remove the cap from the test device and discard the desiccant packets.
2. Have the donor collect his or her urine specimen in the cup to the recommended volume. Make sure that the urine level is at least at the "FILL TO HERE" mark printed on the front of the cup.
3. Read the test results when indicated (see When to Read Test Results Using the "Timer.")



When to Read Test Results Using the "Timer"

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When the "RESULT READY" window is completely filled with red color, or is almost completely covered with red color that reaches the top of the window, the test results are ready to interpret.

When red color becomes clearly visible at the bottom of the "RESULT EXPIRED" window, test results should no longer be interpreted and should not be considered as conclusive.

Interpretation of Test Results

Negative Test Results For All Drugs Tested

Negative – A negative result is indicated when two (2) colored bands appear, one in the Control Region (C) and one in the Test Region (T), *before* any red color appears at the bottom of the "RESULT EXPIRED" window. This result indicates that the target drug is not present or its concentration is below the detection sensitivity of the test panel. Some negative results may appear in as little as 1 minute, and can be safely interpreted as soon as 2 colored bands are visible.

Positive Test Results For Amphetamine & THC

Positive – A positive result is indicated when only one (1) colored band appears in the Control Region (C) and no band appears in the Test Region (T), *before* a red spot appears in the "RESULT READY" window. This result indicates that the target drug concentration is at or above the detection sensitivity of the panel. More than one panel may be positive. Potentially positive results can only be reported when a red spot appears in the timer's "RESULT READY" window, and *before* any red color appears at the bottom of the timer's "RESULT EXPIRED" window.

Invalid Test Results For Cocaine & Opiates

Invalid – A test must be considered invalid if, *after* a red spot appears in the "RESULT READY" window, no bands appear or if a band appears in the Test Region without a Control Band. The presence of a Control Band is necessary to confirm assay performance.

Exhibit H

Quality Control

An internal procedural control line has been incorporated into the test device to help ensure proper kit performance and reliability. However, the use of external controls is recommended. Positive and negative controls within 25% of the cutoff concentration should produce the expected results. For positive controls, only one (1) colored band will appear in the Control Region (C), and no band will appear in the Test Region (T). For negative controls, two (2) colored bands will appear, one in the Control Region (C) and one in the Test Region (T).

Limitations of the Procedure

1. It is possible that substances and factors not described in this directional insert may interfere with the test, causing false results (*e.g.* technical or procedural error).
2. This test has been developed for testing urine samples only. Its performance using other specimens has not been substantiated.
3. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, a new sample must be obtained.
4. All preliminary positive results must be confirmed by another method. Gas chromatography/mass spectrometry (GC/MS) is the method of choice to confirm the presence and concentration of a drug in urine.
5. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of target drugs or the level of intoxication.
6. Because QuickScreen™ is a competitive assay no prozone effect is present.
7. Occasionally, samples containing target drugs below the target drug's cutoff sensitivity for the test may produce a positive result.

Performance Characteristics

Sensitivity – The sensitivity of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent clinical laboratories are reported for overall sensitivity, comparing QuickScreen™ to the Emit II instrument-based immunoassay.

Specificity – The specificity of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent clinical laboratories are reported, comparing QuickScreen to the Emit II assay.

Accuracy – The accuracy of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent laboratories are reported, comparing QuickScreen to the Emit II assay.

	In-House Study, % Agreement					Clinical Study, % Agreement				
Analyte	PCP	AMP	THC	COC	OPI	PCP	AMP	THC	COC	OPI
n =	167	189	143	164	176	140	124	102	143	151
Sensitivity	99	97.6	99	100	>99	95	98.8	98	100	>99
Specificity	99	100	99	95.9	>99	99	100	99	87.5[1]	>99
Accuracy	>99	99.4	98	98.1	>99	97.9	99.2	>98	96.5	>99

[1] Five discrepant results were observed in the Cocaine Clinical Study. The samples were from 3 to 10% below the assay cutoff concentration (271 to 293 ng/mL) and subsequently tested positive by GC/MS.

Precision – Eight urine pools, ranging in concentration from 0 to 200% of cutoff, were assayed twice a day for 20 days. The results were interpreted individually by two technicians. The inter- and intra-assay coefficients of variation were determined to be less than 2%.

Cross-Reactivity – The following structurally related compounds were spiked into normal human urine and found to cross-react in the QuickScreen Pro Multi Drug Screening Test. The results, in µg/mL, are expressed as that amount of compound capable of giving a result equivalent to the target drug at its cutoff concentration. Unless otherwise noted, a blank space indicates no interference was observed when the compound was tested to 100 µg/mL.

Compound	PCP	AMP	THC	COC	OPI
2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP)	25				
Phencyclidine	0.025				
d-Amphetamine		1			
dl-Amphetamine • 3-Hydroxytyramine • (±)-α-Phenylethylamine		10			
l-Amphetamine • Mephentermine • (R)-(+)-α-Phenylethylamine		100			
(±)-3,4-Methylenedioxyamphetamine		4.5			
β-Phenylethylamine		10			
Tyramine		12.5			
11-Hydroxy-Δ9-THC[a]			1		
11-Nor-Δ8-THC-9-Carboxylic Acid[a]			0.1		
11-Nor-Δ9-THC-9-Carboxylic Acid[a] • Δ9-Tetrahydrocannabinol			0.05		
Δ8-Tetrahydrocannabinol			100		
Benzoylecgonine • Cocaine				0.3	
Metoclopramide				25	
Procaine • Pyrilamine				100	
6-Acetylmorphine • Hydromorphone					10
Codeine					1
Ethylmorphine[b] • Morphine • Nalorphine					2
Heroin[b] • Hydrocodone					2.5
Morphine-3-β-D-Glucuronide					5

[a] A blank space indicates that no cross-reactivity was observed when the compound was tested to 3 µg/mL.

[b] A blank space indicates that no cross-reactivity was observed when the compound was tested to 10 µg/mL.

Interfering Substances – The following compounds were spiked into normal human urine and tested for interference with the QuickScreen™ Pro Multi Drug Screening Test. Unless otherwise noted, these compounds were tested to 100 µg/mL with no interference observed.

Acetaminophen • Acetone • *N*-Acetylprocainamide • Acetylsalicylic Acid (Aspirin) • Albumin • Alphenal • Alprazolam[c] • Amantadine • (+)-Amethopterin • Amikacin • *dl*-Aminoglutethimide • Aminopyrine • Amitriptyline • Amobarbital • Amoxicillin • Ampicillin • Apomorphine • Aprobarbital • (–)-Arterenol • *l*-Ascorbic Acid (Vitamin C) • Aspartame • *d*-Aspartic Acid • *dl*-Aspartic Acid • *l*-Aspartic Acid • Atropine • Barbital • Barbituric Acid • Benzoic Acid • Benzphetamine • Benztropine Methane Sulfonate • Bilirubin • Bromazepam • Bromocriptine Mesylate • (+)-Brompheniramine • Butabarbital • Butalbital • Butethal • Caffeine • Cannabidiol • Cannabinol • Carbamazepine • Cephalexin • Chloramphenicol • Chlordiazepoxide • Chloroquine • (+)-Chlorpheniramine • (±)-Chlorpheniramine • Chlorpromazine • Chlorpropamide •

Interfering Substances, continued

Chlorprothixene • Cimetidine • Clemastine • Clomipramine • Clonazepam • Clonidine • (–)-Cotinine • Creatinine • Cyclizine • Cyclobenzaprine • Cyclosporin A • Cyproheptadine • (–)-Deoxyephedrine • Desipramine • Desmethyldiazepam • Dextromethorphan • 5,5-Diallylbarbituric Acid • Diazepam • Diflunisal • Digoxin • 4-Dimethylaminoantipyrine • Diphenhydramine • Diphenoxylate • 5,5-Diphenylhydantoin • Disopyramide • Doxepin • Doxylamine • (+)-ψ-Ephedrine • (–)-ψ-Ephedrine • (+)-Ephedrine • (±)-Ephedrine • (–)-Ephedrine • (±)-Epinephrine • (+)-Epinephrine • Erythromycin • Estriol • Estrone-3-Sulfate • Ethanol • Ethosuximide • Ethyl-*p*-Aminobenzoate • Ethylenediaminetetraacetic Acid • Fenfluramine • Fenoprofen • Fentanyl[d] • Flunitrazepam • Flurazepam • Furosemide • Gentamicin • Gentisic Acid • Glucose • *dl*-Glutethimide • Griseofulvin • Guaiacol Glyceryl Ester • Hexobarbital • Human Hemoglobin • Hydrochlorothiazide • *o*-Hydroxyhippuric Acid • 5-Hydroxyindole-3-Acetic Acid • 5-Hydroxyindole-2-Carboxylic Acid • Hydroxyzine • Ibuprofen • Imipramine • Indole-3-Acetic Acid • Indole-3-Butyric Acid • Indomethacin • (+)-Isoproterenol • (±)-Isoproterenol • (–)-Isoproterenol • Isoxsuprine • Kanamycin • Ketamine • Ketoprofen • Labetalol • Levorphanol • Lidocaine • Lithium Carbonate • (±)-Lorazepam • Lormetazepam • Lysergic Acid Diethylamide (LSD)[e] • Medazepam • Melanin • Meperidine • Meprobamate • Mescaline • *dl*-Metanephrine • (±)-Methadone • (+)-Methamphetamine • Methaqualone • (S)-6-Methoxy-α-Methyl-2-Naphthaleneacetic Acid • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*dl*-Alanine • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*l*-Alanine • (±)-3,4-Methylenedioxymethamphetamine • Methylphenidate • Methyprylon • (±)-Metoprolol • Nafcillin • Naloxone • Naltrexone • Naphazoline • α-Naphthaleneacetic Acid • β-Naphthaleneacetic Acid • Naproxen • Netilmicin • Niacinamide • Nialamide • Nicotinic Acid • Nifedipine • Nitrazepam • Nomifensine • Norcodeine • Nordoxepin[d] • Norethindrone • Normorphine[c] • Nortriptyline • Noscapine • Nylidrin • Orphenadrine • Oxalic Acid • Oxazepam • Oxycodone • Oxymetazoline • Papaverine • Penicillin G • Pentazocine • Pentobarbital • Phenelzine • Pheniramine • Phenobarbital • Phenothiazine • Phentermine • Phenylacetone • *l*-Phenylalanine • Phenylbutazone • *trans*-2-Phenylcyclopropylamine • *l*-Phenylephrine • (±)-Phenylpropanolamine • Piroxicam • Potassium Chloride • Prazepam • Prednisolone • Primidone • Procainamide • Prochlorperazine • Promazine • Promethazine • (+)-Propoxyphene • 2-Propylpentanoic Acid • Protriptyline • Quinidine • Quinine • Ranitidine • Riboflavin • Salicylic Acid • (–)-Scopolamine • Secobarbital • Sodium Chloride • Sulindac • Temazepam • Terbutaline • Tetracycline • Tetraethylthi-

uram Disulfide (Antabuse) • Tetrahydrozoline • Thebaine • Theophylline • Thioridazine • *cis*-Thiothixene • Tobramycin • Triamterene • Triazolam[d] • Trifluoperazine • Triflupromazine • *dl*-Trihexyphenidyl • Trimethobenzamide • Trimethoprim • Trimipramine • Triprolidine • Urea • Uric Acid • Vancomycin • (±)-Verapamil • Zomepirac

[c] No interference was observed when the compound was tested to 25 µg/mL.

[d] No interference was observed when the compound was tested to 10 µg/mL.

[e] No interference was observed when the compound was tested to 2.5 µg/mL.

Bibliography & Suggested References

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